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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,349	12/06/2000	Sreekant Nadkarni	01-678	9200

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EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/731,349	Applicant(s) NADKARNI ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of receipt is made of the applicant's declaration, power of attorney, and petition for extension of time under 37 CFR 1.136(a), along with all appropriate fees. The above were all received on July 26, 2001, for Application No. 09/731,349. Acknowledgement of receipt is also made of the applicant's associate power of attorney, received on August 27, 2001, for this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao *et al.* (WO 00/32189) in view of Lai *et al.* (U.S. Patent Number 6,306,842 B1) and Delgado, III *et al.* (U.S. Patent Number 6,323,226 B1).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Gao *et al.* teaches a pharmaceutical composition in an orally administrable form comprising celecoxib, a cyclooxygenase-2 inhibitory drug, in amounts of about 10 mg to about 1000 mg (See Page 4, Lines 1-5). This composition shows similar pharmacokinetics to those presented in the claims of the application (See Page 4, Lines 6-15, and Page 5, Line 24 to Page 6, Line 5). Gao *et al.* also teaches embodiments of the composition with a distribution of the particle sizes of the drug such that the D_{90} is most preferably less than 25 μm. This reference also teaches that the drug particles in the composition have a mean particle size of about 1 μm to about 10 μm (See Page 6, Line 30 to Page 7, Line 11; and Page 30, Lines 8-18). Gao *et al.* also describes the usefulness of such a composition, administered once or twice a day, in the treatment and prevention of a wide range of medical conditions and disorders mediated by cyclooxygenase-2 (See Page 8, Line 22 to Page 12, Line 24; and Page 15, Line 25 to Page 17, Line 33; and Page 32, Lines 1-25). This composition comprises pharmaceutically acceptable excipients comprising diluents (including microcrystalline cellulose and lactose monohydrate), disintegrants (including croscarmellose sodium), binding agents (including pregelatinized starch), and lubricants (including magnesium stearate) in the same proportions as disclosed in Claim 5 (See Page 18, Line 5 to Page 30, Line 7). This composition can also comprise, in addition to celecoxib, opioid or analgesic drugs for use in a combination therapy (See Page 12, Line 25 to Page 13, Line 4). The reference discloses the process outlined in Claim 11, comprising the steps of wet granulating the drug with diluents and a binding agent, drying the resulting granules, and compressing the granulate to form a tablet (See Page 34, Line 2, to Page 37, Line 28). Furthermore, Gao *et al.* also teaches that in the preparation of the composition, that

all or a portion of one or more of the excipients may be alternatively added during a second blending step, after the drying step, for example (See Page 33, Line 17 to Page 34, Line 1).

Gao *et al.* is silent with respect to valdecoxib. However, Lai *et al.* (See Column 5, Lines 19-24) and Delgado, III *et al.* (See Column 2, Lines 35-42 and Column 5, Line 66 to Column 6, Line 19) both group celecoxib and valdecoxib into a general group of cyclooxygenase-2 inhibitors. Therefore, the examiner is of the opinion that celecoxib and valdecoxib are similar enough, in terms of chemical and pharmaceutical properties, to be used interchangeably in the pharmaceutical composition presented in the application.

Thus, it would have been prima facie obvious for one of ordinary skill in the art to use the teachings of Gao *et al.* in view of Lai *et al.* and Delgado, III *et al.* to formulate a similar pharmaceutical composition which comprises valdecoxib instead of celecoxib as the cyclooxygenase-2 inhibitory drug.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

THURMAN K. PAGE
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